K990672

Hurricane Medical
2331K 63rd Avenue East
Bradenton, FL 34203
941-751-0588
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MAY 18 1999

510(k) Summary
Lacrimal Intubation Sets and DCR Sets

CONFIDENTIAL

March 26, 1999
Contact Person: David A. Clapp

Classification Name: Unknown
Common Name: Lacrimal Intubation Set, Dacryocystorhinostomy (DCR) Set

Classification: Unknown

Substantial Equivalent: The referenced devices manufactured and distributed by Hurricane Medical are substantially equivalent to:

Lacrimal Intubation Set manufactured and distributed by JEDMED

Canaliculus Intubation Set manufactured and distributed by SOLAN

Lacrimal Intubation Set and DCR Set manufactured and distributed by VISITEC

Description: The referenced devices consist of two pieces of the same gauge size and length 300 series stainless steel wire (20G or 23G) both connected to a common piece of medical grade silicone tubing by friction fit, gluing, or crimping.

Intended Use: These devices are by an oculoplastic surgeon to reconstruct the lacrimal outflow system due to injury or malformation of the lacrimal drainage system, dacryocystorhinostomy which is the construction of a new tear drainage channel from the lamrical sac into the nose , and other lacrimal system reconstruction. The stainless steel probe followed by the silicone tubing is used by the oculoplastic surgeon to navigate completely through the tear drainage channel. The stainless steel probe is retrieved at the opposite end of the tear drainage channel inside the nasal cavity and is removed from the silicone tubing. The silicone tubing is secured and left in place within the tear drainage channel. Post-Op assessment by the oculoplastic surgeon determines when the silicone tubing is removed.

Literature Review:

During the past several decades, several methods and materials have been used to temporarily splint portions of the lacrimal drainage system as treatment for injuries or obstructions.

In 1959, Huggert first described intubation of the lacrimal drainage system. Acta Ophthalmology, 1959, 37:355-358.

In 1977, Crawford described a method for intubating the lacrimal system by using silicone tubing attached to a stainless steel probe on each end. After inserting the probes through the canaliculi into the nostril, the ends of the silicone were cut and tied. They were then left in place for up to six months. Canadian Journal of Ophthalmology, 1977; 12:289-292.

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Dacryocystorhinostomy (DCR) as defined in the Dictionary of Eye Terminology is the construction of a new tear drainage channel from the lacrimal sac into the nose. Hurwitz describes a DCR procedure in which the silicone tubing is left in place for four months. Canadian Journal of Ophthalmology, 1982; 17:13-16.

Flanagan describes a DCR procedure where the silicone tubes were left in place for six months to allow scar tissue to form. Oculoplastic Surgery Strabismus and Pediatric Ophthalmology, 1990.

Reifler reports that silicone tubing has achieved great popularity and is viewed by many experts as the canalicular stent material of choice.

Technological characteristics as compared to predicate devices:

Characteristic	Hurricane Medical	JEDMED	SOLAN	VISITEC
Probe Material	Stainless Steel Wire	Stainless Steel Wire	Stainless Steel Wire	Stainless Steel Wire
Probe Size (DxL) Probe Size (DxL)	0.025" x 7" 0.90" x 1.75"	0.016" x 4" N/A	0.051" x 6" N/A	0.025" x 7" 0.90" x 1.75"
Tubing Material Rod Material	Medical Grade Silicone Medical Grade Silicone	Medical Grade Silicone	Silicone	Silicone Silicone
Tubing Size (DxL) Rod Size (DxL)	0.025" x 13" 0.080" x 15"	0.025" x unknown N/A	Unknown x 12" N/A	0.025" x 14" 0.080" x 15"
Adhesive Used	Yes	Yes	Yes	Yes
Probe Ends	Rounded?Blunt	Olive Shaped (Rounded)	Rounded/Blunt	Rounded/Blunt
Probe Malleability	Excellent	Excellent	Excellent	Excellent
Surgical Uses	Single	Single	Single	Single
Package Type	Tyvek Pouch	Tyvek Pouch	Tyvek Pouch	Tyvek Pouch
Packaged Sterile	Yes	Yes	Yes	Yes

Safety Charactoristics: These devices are used only by oculoplastic surgeons who are experts in this dicipline of reconstructive surgery. The use of a malleable stainless steel probe allows the surgeon to form the probe as needed. The probes contain a radius/blunt end to allow a smooth passage through the tear drainage channel. The silicone tubing following the stainless steel probe contains an equal or less diameter than the stainless steel probe. This allows the silicone tubing to easily follow the probe. The silicone tubing is friction fitted over the stainless steel probe as well as bonded with glue. This minimizes the risk of the silicone tubing becoming seperated from the stainless steel probe during the navigation through the tear drainage channel. The silicone tubing and adhesive are medical grade. The devices are packaged in water impermable and tear resistant tyvek/poly pouches that are heat sealed. The sterilization process ensures at least a 10^{-6} sterility assurance level (SAL).

The literature review included in this summary has demonstrated that information regarding surgery to the lacrimal system has been published as far back as 1959. Devices used in these surgical procedures were commonly constructed from stainless steel wire and silicone tubing. The referenced literature has also shown that the referenced device may be safely and effectively be used by a competent oculoplastic surgeon to reconstruct the lacrimal outflow system, dacryocystorhinostomy, and other lacrimal system reconstruction.many situations that are deemed appropriate.

The Hurricane Medical Lacrimal Intubation Sets and Dacryocystorhinostomy (DCR) Sets have equivalent technological characteristics as the proposed predicate devices. Each identified can be seen in the above chart and thus demonstrates substantial equivalence to a legally marketed device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 18 1999

Mr. David A. Clapp
Regulatory Affairs Head
Official Correspondent
Hurricane Medical
2331K 63rd Avenue East
Bradenton, FL 34203

Re: K990672 and A1 and A2
Trade Name: Lacrimal Intubation Set and
Dacryocystorhinostomy (DCR) Set
Regulatory Class: Unclassified
Product Code: 86 HNL
Dated: February 23, March 9, and March 26, 1999
Received: March 2, March 12, and April 5, 1999

Dear Mr. Clapp:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594- 4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Nancy C Brogdon for

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number : K990672

Device Name: Lacrimal Intubation Set, DCR Set

Indications For Use:

These devices are used in ophthalmic surgery to reconstruct the lacrimal outflow system, dacryocystorhinostomy, and other lacrimal system reconstruction.

(PLEASE DO NOT WRITE BELOW THIS LINE –CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, office of Device Evaluation (ODE)

Prescription Use__℞__ or Over-the –counter use_____

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K990672